

## **REMARKS/ARGUMENTS**

Reconsideration of this application is requested. Claims 1, 2, 5-7, 9-13, 15-22, 24-25, 28, 29, 31-35 and 37-42 are in the case.

### **I. DRAWINGS**

The drawings have been objected to for the reasons detailed in paragraphs 3-5 of the outstanding Official Action. In response, the specification has been amended to include reference to the numerals noted by the Examiner on pages 2 and 3 of the Action. Claims referring to the "foundation layer" have been cancelled without prejudice. Withdrawal of the objection to the drawings is now respectfully requested.

### **II. SPECIFICATION**

A new title is presented, together with an Abstract on a separate sheet attached to this response. In addition, the objections to the disclosure outlined in paragraph 7 on page 3 of the Action have received attention. The specification has been amended to include customary headings, including a Brief Description of the Drawings. No new matter is entered.

### **III. CLAIM OBJECTIONS**

Claims 2, 3, 5 and 6 have been objected to for the reasons detailed in paragraph 9 of the Action. In response, the amendments suggested by the Examiner have been adopted.

Claim 19 has been amended to replace “carry” with “carrier”, and claim 23 has been cancelled without prejudice. Claims 26 and 43 have also been cancelled without prejudice. Withdrawal of the claim objections is now respectfully requested.

**IV. THE 35 U.S.C. §112, SECOND PARAGRAPH, REJECTION**

Claims 1-23, 30, 36 and 41 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite for the reasons detailed on pages 5 and 6 of the Action. Without conceding to the merit of these rejections, the claims have been amended to improve their form. The following comments are offered.

Claims 3, 8, 14, 23, 30 and 36 have been cancelled without prejudice. Withdrawal of the rejections relating to those claims is accordingly respectfully requested.

Claims 1, 20 and 41 have been amended to deal with the antecedent basis point raised by the Examiner. Withdrawal of the outstanding 35 U.S.C. §112, second paragraph, rejection is now respectfully requested.

**V. THE OBVIOUSNESS REJECTION**

Claims 1, 3-7, 9, 10, 17-22, 24, 26-29, 31, 32 and 38-43 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over WO 98/18387 to Joseph in view of U.S. Patent 6,106,473 to Violante et al. That rejection is respectfully traversed.

The invention provides an instrument insertable into a medium and capable of detection by sonic imaging equipment. The instrument includes an elongate member for insertion into the medium, and having a region the position of which it is desirable to

monitor; and a bubble generator for generating a plurality of discrete mobile bubbles at the region, whereby the bubbles are detectable by sonic imaging equipment. The bubble generator comprises two elements which, upon contact with each other in the presence of a fluid, react with each other to produce gas bubbles. The elements comprise first and second radially displaced layers of the elements within a fluid permeable carrier material.

Joseph and Violante fail to disclose or suggest the claimed invention, and would not have been combined by a person of ordinary skill in this art. Joseph relates to the generation of bubbles, when a needle is exposed to a liquid medium. In contrast, Violante is concerned with a structure in which the bubbles have been preformed and entrapped in the coating of the needle (see, for example, Abstract, last sentence; column 3, lines 20-21). Thus, any modification of Joseph in view of Violante would involve preforming the bubbles in Joseph, which is completely contrary to Joseph.

Moreover, the present invention enjoys several advantages over Violante. When providing trapped bubbles, such as those formed by Violante, the optimum bubble size and distribution must be carefully selected to provide the best ultrasound scattering characteristics. In practice, this is quite difficult, with little mechanism for accurate control of bubble size and distribution.

The "dynamic" formation of bubbles *in situ* provided by the present invention offers many advantages over "static" bubbles. The coated needle or device, when introduced into the tissues, absorbs fluid which, with the mixing of the reactive materials, produces micro bubbles within the coating. The micro bubbles grow from virtually zero size to a maximum diameter, with the optimum bubble size being present

in this range. Bubble production is a random process. Hence, some bubbles of optimum size would also be optimally spaced to give the combination of the optimum size and distribution to give maximum scatter. The intensity of scattered sound from the bubbles formed in the coating on device should be significantly higher than that from the surrounding tissues so that it stands out in sharp contrast against the background.

For all of these reasons, it is believed that one of ordinary skill would have had no motivation to combine Violante with Joseph in the context of the presently claimed invention. Withdrawal of the obviousness rejection based on those two references is accordingly respectfully requested.

Claims 2, 11-13, 25 and 33-35 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Joseph in view of Violante and further in view of U.S. Patent 5,912,012 to Carlin et al. Claims 15 and 37 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Joseph in view of Violante and further in view of U.S. Patent 5,885,281 to Urueta. Claim 16 stands rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Joseph in view of Violante and Urueta and further in view of U.S. Patent 5,786,069 to Ljungberg et al. Those rejections are respectfully traversed.

The Examiner asserts that the intermediate layer defined in claims 2 and 25 is shown in Carlin. The Examiner appears to be making reference to the layer 16 of Carlin which is defined as a layer which "is not chemically involved with the effervescent reaction" (column 3, lines 22-24). Carlin is completely silent on the permeability of layer 16 and certainly contains no disclosure or suggestion that layer 16 is a fluid permeable layer. The chemical involvement of the layer is irrelevant to its fluid permeability.

With regard to the remaining rejections, the above-discussed deficiencies of

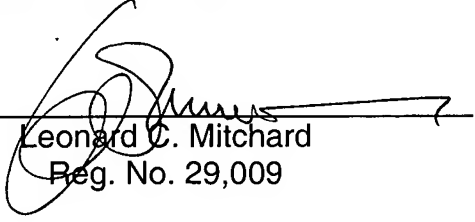
Joseph and Violante are not cured by the secondary references relied on by the Examiner. It is clear therefore that one of ordinary skill would not have been motivated to combine the disclosures of Joseph and Violante, with or without the cited secondary art. Absent any such motivation, no *prima facie* case of obviousness is generated in this case. Reconsideration and withdrawal of the outstanding obviousness rejections are accordingly respectfully requested.

Favorable action on this application is awaited.

Respectfully submitted,

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